

Appl. No. 09/926,375  
Response dated October 11, 2005  
Reply to Office action of August 12, 2005.

### **REMARKS/ARGUMENTS**

By the present amendment, claims 1-12, 17, 19, 23, 29 and 30 have been amended and claims 13-16 and 18 have been canceled. The amendments to the claims have been made without prejudice and without acquiescing to any of the Examiner's objections. Applicant reserves the right to pursue any of the deleted subject matter in a further divisional, continuation or continuation-in-part application. No new matter has been entered by the present amendment and its entry is respectfully requested.

The Official Action dated August 12, 2005 has been carefully considered. It is believed that the amended specification and claims and the following comments represent a complete response to the Examiner's rejections and place the present application in condition for allowance. Reconsideration is respectfully requested.

### **Claim Objections**

The Examiner has objected to claims 1, 13 and 19 as the preamble related to non-human animals while the body of the claims recite mammalian species. In response, the claims have been amended in order to replace the term "animal" with "mammal" as requested by the Examiner.

### **Double Patenting**

The Examiner has advised that claims 15 and 16 would be rejected as claiming the same inventions as claims 1 and 3 should claims 1 and 3 be found allowable. In response, claims 15 and 16 have been canceled which overcomes the objection.

### **35 USC§112, First Paragraph**

The Examiner has maintained the rejection of claims 1-11, 13-17, 19, 22, 24, 27, 29-31 and 33-35 under 35 USC§112, First Paragraph as lacking enablement for the entire scope of the claims. The Examiner reiterates two of the grounds of rejection raised in the first office action and also raises a new ground of objection. Each of these are addressed in turn below.

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The Examiner has objected to claims 15, 30, 31 and 33-35 as not being enabling for non-mammalian species including fish and birds. In response, claim 30 has been amended in order to specify a mammal selected from the group consisting of pigs, goats, sheep, cows and horses. Claims 31 and 33-35 depend from claim 30 and therefore also contain the same limitation. Claim 15 has been canceled.

Second, the Examiner has objected to claims 13, 14 and 17 as failing to provide full transgene expression in the salivary glands. Claims 13 and 14 have been deleted by the present amendment. Claim 17 has been amended in order to depend from Claim 1 which does require secretion in the salivary glands. Claim 17 further specifies that the phytase is also secreted in the gastrointestinal tract of the mammal.

Third, the Examiner has raised a new ground of objection. Specifically, the Examiner has requested that claims 1-11, 13-17, 19, 22-24 and 29 are amended in order to specify that the transgene encodes a secretion signal sequence and that the phytase be expressed and secreted. In response, the claims have been amended without prejudice in order to specify that the transgene contains a signal sequence for secretion of the phytase protein which is expressed and secreted in the salivary glands. We point out that such an amendment does not exclude the possibility that the phytase can be expressed in other tissues of the gastrointestinal tract. As discussed in the response that was filed May 26, 2005, Applicant has shown that while the phytase is secreted from the salivary glands it can also be produced in other tissues such as the fundus region of the stomach, the duodenum, the upper alimentary tract, the respiratory tract mucosa and the reproductive tract.

In view of the foregoing, we respectfully submit that all of the objections to the claims under 35 USC§112, First Paragraph be withdrawn.

**35 USC§112, Second Paragraph**

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The Examiner has objected to claims 19, 22, 24 and 27-29 under 35 USC§112, Second Paragraph as being indefinite. We respectfully disagree with the Examiner for the reasons that follow.

The Examiner has commented that these claims require broader gastrointestinal expression which is not consistent with using a salivary gland specific regulatory sequence. As stated previously, the inventors have shown that when using a regulatory sequence for salivary gland expression of the phytase, the phytase is also expressed in other tissues of the gastrointestinal tract. In order to remove any ambiguity, the claims have been amended in order to remove the word "specific" in reference to this regulatory sequence since it does cause expression in other tissues. Therefore, the claims as amended require that there is expression in the salivary glands but does not exclude that there may be expression in other tissues.

In view of the foregoing, we respectfully submit that all of the objections to the claims under 35 USC§112, Second Paragraph be withdrawn.

### **35 USC§103**

The Examiner has maintained the objection to claims 30, 31 and 33-35 under 35 USC§103(a) as being unpatentable over Mikkelsen (1992) further in view of Velander (1992) and further in view of Pen (1993) as evidenced by Laursen (1997).

The Examiner states that claims 30, 31 and 33-35 do not specify that the animal is a large mammal as recited in the earlier claims. In response, claim 30 has been amended in order to specify that the animal is a mammal selected from a group consisting of pigs, goats, sheep, cows and horses. Claims 31 and 33-35 depend from claim 30 and therefore contain the same limitation.

In view of the foregoing, we respectfully submit that all of the objections to the claims under 35 USC§103 be withdrawn.


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The Commissioner is hereby authorized to charge any fee (including any claim fee) which may be required to our Deposit Account No. 02-2095.

In view of the foregoing comments and amendments, we respectfully submit that the application is in order for allowance and early indication of that effect is respectfully requested. Should the Examiner deem it beneficial to discuss the application in greater detail, she is kindly requested to contact the undersigned by telephone at (416) 957-1682 at her convenience.

Respectfully submitted,

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By 

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